IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BLUE CROSS BLUE SHIELD ASSOCIATION, *et al*., **Plaintiffs,** **vs.** **GLAXOSMITHKLINE LLC,** **Defendant.**	**Civil Action No. 2:13-cv-4663-JS**

[REDACTED] PLAINTIFFS' PRETRIAL MEMORANDUM

Plaintiffs submit this Pretrial Memorandum in accordance with Rule 16(c) of the Court's Local Rules of Civil Procedure.

1. Nature of the Action and Basis for Jurisdiction

Plaintiffs brought this action by filing a writ of summons in the Philadelphia County Court of Common Pleas on July 15, 2011. After Plaintiffs filed their complaint, GSK removed the action to this Court.

Plaintiffs' complaint alleged (a) federal RICO claims; (b) common law fraud; (c) civil insurance fraud under 18 Pa. Cons. Stat. § 4117; (d) breach of express warranty under 13 Pa. Cons. Stat. § 2313; (e) breach of implied warranty of merchantability under 13 Pa. Cons. Stat. § 2314; (f) unjust enrichment; and (g) common law negligent misrepresentation. In addition to compensatory damages, the complaint sought treble damages in connection with Plaintiffs' RICO and civil insurance fraud claims; punitive damages in connection with their common law fraud claim; and attorneys' fees and costs. (Dkt. No. 115; see also Dkt. No. 211 (amended complaint).)

GSK moved to dismiss Plaintiffs' claims under Rule 12(b)(6). This Court denied the motion in a Memorandum and Order dated November 9, 2016. (Dkt. Nos. 105 and 106.) After the close of discovery, GSK moved to dismiss Plaintiffs' claims under Rule 56. The Court granted the motion in part and denied it in part in a Memorandum and Order dated September 30, 2019. (Dkt. Nos. 295 and 296.) The Court dismissed Plaintiffs' RICO and unjust enrichment claims but allowed Plaintiffs to proceed to trial on their remaining claims. The Court has jurisdiction over the claims to be presented at trial under 28 U.S.C. § 1367(a).

2. Statement of Facts

Plaintiffs are 38 insurers (listed in Exhibit A) that collectively supply more than 60% of the U.S. market for private health insurance. Defendant GlaxoSmithKline LLC ("GSK") is one of the world's largest drug companies. GSK sold prescription drugs produced at a plant in Cidra, Puerto Rico, that was owned by a GSK affiliate, SB Pharmco Puerto Rico, Inc. ("SB Pharmco"). The Cidra plant was one of GSK's largest drug sources in the world and accounted for nearly $5 billion in GSK's annual revenue. During the relevant period, 2000 through 2005, Plaintiffs paid more than $2.7 billion for 17 different drugs produced at the Cidra plant (the "At-Issue Drugs").[1]

Under the Food, Drug and Cosmetic Act ("FD&C Act"), drug companies must comply with the Food and Drug Administration's mandatory manufacturing standards -- known as current Good Manufacturing Practices ("cGMPs") -- to "assure" that their products are safe and effective. 21 U.S.C. § 351(a)(2)(B). Plaintiffs allege that GSK misrepresented and concealed the fact that Cidra's products were manufactured in egregious violation of those standards and thus lacked the assurance required by the statute. As a result, the drugs could not be distributed

[1] The 17 drugs are Paxil, Paxil OS, Avandia, Avandamet, Coreg, Bactroban, Kytril, Compazine, Denavir, Dyazide, Dibenzyline, Thorazine, Stelazine, Relafen, Factive, Dyrenium, and Albenza.

or sold legally in the United States. GSK's own cGMP expert admitted in his deposition that no healthcare insurer would knowingly and willingly pay for such drugs. (Dkt. No. 275-1, Plaintiffs' Statement of Material Facts ("SMF"), ¶ 211.) Consequently, the drugs were economically worthless, and Plaintiffs are entitled to recover the full amount they paid for the drugs.

The Cidra plant was originally built in 1978 to manufacture a single drug. By 2004, however, the plant was producing a wide variety of drugs -- in 267 different presentations (distinct drug types, strengths, and packages) -- while running 24 hours a day, seven days a week. GSK distributed and sold Cidra's products throughout the United States. GSK marketed the drugs as "best-in-class" and the "gold standard," asserting their "superior potency, efficacy, and safety profile." (Dkt. No. 295, at 2.)

The FDA conducts intermittent inspections of pharmaceutical plants that produce drugs for U.S. consumption. The FDA inspected the Cidra plant at several points during the relevant period. On each occasion, GSK told the FDA that it had already corrected or was in the process of correcting cGMP violations identified by the inspectors. The evidence will show that serious misconduct at the plant was already occurring at the start of the relevant period, and that GSK was fully aware of the misconduct at all relevant times.

Among other evidence of GSK's ongoing knowledge, Plaintiffs will show that GSK's Manager of Global Quality Assurance, Cheryl Eckard, identified serious and ongoing violations at the plant in 2002 and repeatedly urged GSK's senior management to correct them. After she was terminated for "redundancy" in 2003, she reported her concerns to the FDA. (See Dkt. No. 295, at 9.)

Nevertheless, the violations continued. Following an FDA inspection in late 2004, GSK recalled batches of three drugs: Paxil IR, Paxil CR, and Avandamet. (Dkt. No. 295, at 11.) In response to the Paxil IR recall, GSK created a "Communications Pack" that instructed employees: "Only use the minimum information necessary to satisfy" media inquiries regarding the recall. (Dkt. No. 295, at 10.) Similarly, in response to the Paxil CR and Avandamet recalls, GSK instructed employees to provide information about the recalls only if asked a direct question and to state that GSK "is continuing production at the Cidra site, and [has] every confidence in the quality of the products we manufacture there." (Dkt. No. 295, at 10.)

In March 2005, the FDA and the U.S. Department of Justice seized remaining stocks of Paxil CR and Avandamet. (Dkt. No. 295, at 11.) GSK then devised a "Customer Communication Plan" which recommended that patients substitute Avandia, another drug produced at Cidra, while the Avandamet supply was re-established. (Dkt. No. 295, at 13.) In addition, an internal "Q&A" script regarding the seizure instructed GSK's account managers to warn insurers that GSK would "continue to enforce portfolio contracts during the Avandamet and Paxil CR supply disruptions," and that GSK would view insurers as engaging in "discriminatory conduct" if they encouraged patients or doctors to switch to competitors' products. (Dkt. No. 295, at 14.) GSK continued to downplay the extent of the problems at Cidra and assure the public that it was cooperating with the FDA to resolve the FDA's issues. (Dkt. No. 295, at 10.)

When the FDA seized remaining stocks of Paxil CR and Avandamet, it advised patients to continue taking their current supply of tablets while consulting their doctors about alternatives. (Dkt. No. 221, ¶ 192.) This reflected the FDA's view that risks posed by cGMP violations may be outweighed by the risks posed by an abrupt termination of therapy. In these circumstances,

the FDA must choose the lesser of two evils. The FDA's advice that patients should continue taking their tablets did not mean that the cGMP violations were trivial or insubstantial. (Dkt. No. 215-3, at 7.)

In May 2005, the FDA entered into a consent decree with GSK and SB Pharmco. Among other things, the consent decree required that GSK engage a third-party auditor to evaluate cGMP compliance at Cidra. (Dkt. No. 295, at 14.) Pursuant to that requirement, GSK hired Quantic Regulatory Services ("Quantic"). Quantic issued a report to the FDA detailing 346 areas of cGMP non-compliance -- substantially more than the FDA had found during its years of inspections at Cidra. GSK acknowledged that Quantic's inspection of the plant was "200 times greater" than typical FDA inspections. (Dkt. No. 221, ¶ 59.)

GSK closed the plant in 2009. In 2010, SB Pharmco pled guilty to the felony of shipping adulterated drugs with fraudulent intent in violation of the FD&C Act. The underlying misconduct included: (1) releasing bacteria-contaminated drugs intended for cancer patients, infants, and other vulnerable patients; (2) releasing a chronically super-potent and sub-potent diabetes drug; (3) product mix-ups (different drugs or potencies in the same container); and (4) repeated interference with the plant's Quality Assurance staff by Cidra's Site Director. (Dkt. No. 221, ¶ 16.)

The guilty plea resulted in a $150 million fine and forfeiture. In addition, GSK paid $600 million to settle related civil claims by federal and state healthcare programs, which had paid for many of the same drugs at issue here. GSK and the government agreed that neither the criminal penalty nor the civil settlement included any restitution for private insurers because it was too difficult to make the necessary calculations in the government proceedings. (Dkt. No. 221, ¶ 19.)

GSK also agreed to accept SB Pharmco's explicit admissions of guilt and to avoid taking any positions inconsistent with those admissions. (Dkt. No. 221, ¶ 20.)

3. Computation of Monetary Damages

Plaintiffs have calculated monetary damages as follows: [2]

Plaintiff	Total Amount Paid for At-Issue Drugs During the Relevant Period
Aetna	$483,720,256
AvMed	$13,618,843
BCBS AL	$105,354,079
BCBS Association	$211,637,748
BCBS FL	$41,380,581
BCBS KC	$15,144,561
BCBS MA	$106,713,622
BCBS MN	$78,629,050
BCBS NC	$89,175,648
BCBS RI	$17,122,591
BCBS SC	$20,788,386
BCBS TN	$63,520,084
CareFirst GHMS	$65,609,427
CFM	$4,166,516
CIGNA	$402,969,483
Emblem	$11,142,151
GEHA	$52,410,763
GHC KPS	$22,717,992
Health Net	$110,199,246
HealthNow	$35,442,801
Highmark Highmark BCBSD Highmark WV	$137,472,890
BCBS LA	$7,206,665
MMOH	$50,386,738

[2] The following Plaintiff entities are consolidated as one for purposes of this action in view of their corporate structure and/or mergers and acquisitions: (i) CareFirst and GHMS; (ii) Highmark, Highmark BCBSD, Highmark WV; (iii) Usable and HMO; (iv) Wellmark and Wellmark IA; and (v) Wellpoint and Amerigroup.

Noridian	$4,535,905
Premera	$19,502,368
Priority	$22,045,865
Regence	$76,615,011
Usable HMO	$9,981,185
Wellcare	$10,722,857
Wellmark Wellmark IA	$19,581,104
Wellpoint Amerigroup	$426,546,664
Total	**$2,736,061,080**

Interest on these amounts continues to accrue at the default rate on a per diem basis. *Reed Associates, Inc. v. Takton Development Corp.*, No. 464 EDA 2017, 2017 WL 4220088, at *4 (Sup. Ct. Pa. Sept. 22, 2017) (holding that prejudgment interest in an equitable remedy that may be awarded when a defendant holds money which belongs to the plaintiff). In addition, as noted above, Plaintiffs seek punitive damages, treble damages, attorneys' fees and costs.

4. Witnesses

A list of the liability and damage witnesses that Plaintiffs anticipate offering at trial via live testimony, videotaped testimony, or through deposition testimony is attached hereto as Exhibit B.

Plaintiffs reserve the right to call any of the witnesses identified by GSK and the right to call additional witnesses in rebuttal, the identity of whom cannot be known until the presentation of GSK's case.

Plaintiffs also reserve the right to call as witnesses any individuals identified by GSK in its pretrial memorandum.

5. Schedule of Exhibits

A schedule of the exhibits that Plaintiffs anticipate offering at trial is attached hereto

as Exhibit C.

Plaintiffs reserve the right to utilize any documents identified, referred to, or mentioned in any and all discovery responses, deposition testimony in this matter, attached exhibits to deposition transcripts, made available in discovery or through disclosures of GSK and Plaintiffs. Plaintiffs also reserve the right to use any non-exhibit version of any deposition exhibit included on Exhibit C. Plaintiffs also reserve the right to use certified translations.

Plaintiffs also reserve the right to use as trial exhibits any materials identified by GSK in its pretrial memorandum, and the right to use documents not identified as exhibits for impeachment purposes.

Furthermore, Plaintiffs reserve the right to supplement their exhibit list and the right to identify additional exhibits in rebuttal, the identity of which cannot be known until the presentation of GSK's case.

6. Estimated Time for Trial

Plaintiffs estimate that presentation of their case-in-chief will require 3 weeks.

7. Special Comments Regarding Legal Issues, Stipulations, Amendments of Pleadings, or Other Appropriate Matters

A. Opening and Closing Statements

Pursuant to Section III, Subsections I and O of the Court's Policies and Procedures, Plaintiffs respectfully request 45 minutes to present their opening statement, and 60 minutes to present their closing statement (inclusive of rebuttal).

B. GSK's Motions in Limine

GSK filed 10 motions in limine. Two of the motions -- Dkt. No. 313, seeking to preclude claims based on "out-of-state" transactions, and Dkt. No. 314, seeking to preclude claims on behalf "self-funded" customers -- are designed to inject complexity into the litigation on the eve

of trial. As explained in Plaintiffs' oppositions (filed contemporaneously with this memorandum), both arguments have been waived because GSK neglected to raise the grounds for the motions in in its Rule 12(b)(6) motion (Dkt. No. 38-2), in its answer to the complaint (Dkt. No. 115), and in its Rule 56 motion (Dkt. No. 270).

If the Court nonetheless grants the motions, Plaintiffs are prepared to meet the additional burdens, but we note that such rulings would cause a seismic shift in the timing, structure, and scope of the trial. They would substantially affect who the parties to the case are, what the claims at issue are, and what state laws apply to those claims -- all of which would affect the jury instructions and the verdict slip, not to mention the parties' presentations of their case.

For example, if the Court granted GSK's motion to preclude claims on behalf of Plaintiffs' self-funded customers, under Fed. R. Civ. P. 17(a), the Court would have to allow a "reasonable time" for Plaintiffs' self-funded customers, who number in the thousands, "to ratify, join, or be substituted into the action." That would delay the trial indefinitely, impose unnecessary burdens on the Court, and cause undue prejudice to Plaintiffs. Moreover, to the extent that self-funded customers decided to join as parties, the Court would be required to develop further procedures and adjust the trial structure accordingly. GSK cannot justify its delay in making this motion until 21 days before trial.

Similarly, if the Court accepted GSK's argument regarding claims based on "out-of-state" transactions, the result would ***not*** be GSK's requested claim "preclusion," but rather the trial of those claims under the laws of 49 other states, with the necessary jury instructions regarding those laws. GSK has failed to propose any such instructions, which confirms that it has waived its motion. (Furthermore, GSK ignores the fact that Plaintiffs' burden of proof with respect to a large portion of their fraud claims would be reduced as a result from Pennsylvania's

"clear and convincing" standard to a "preponderance" standard.) Additionally, Plaintiffs' damages expert, Dr. Conti (and presumably GSK's damages expert) would need to adjust her report to include state-by-state damages.

If necessary, Plaintiffs would be prepared to meet these last-minute burdens imposed by GSK, but they are unnecessary for the basic reason that GSK has waived both motions.

C. The Admissibility of Statements by GSK

In addition to the legal issues raised in the pending motions before the Court, Plaintiffs anticipate that the Court will be required to decide whether the statements listed below are admissible against GSK.[3] Despite the October 21, 2010 Side Letter between GSK and the U.S. Department of Justice in which GSK explicitly agreed not to make any statements inconsistent with the explicit admission of guilt by SB Pharmco, counsel for GSK has repeatedly tried to distance itself from SB Pharmco's guilty plea. Accordingly, Plaintiffs anticipate that they will seek to admit contrary evidence, including, along with other proof, the following statements and information:

Statements in GSK's 56.1 Statement, including:

- "In January 2001, Glaxo Wellcome plc and SmithKline Beecham merged to form GlaxoSmithKline plc. Am. Compl. ¶ 56." GSK SUMF ¶ 59.
- "SB Pharmco and GSK are both indirect subsidiaries of GlaxoSmithKline plc. Am. Compl. ¶¶ 3, 55, 56." GSK SUMF ¶ 60.
- "SB Pharmco manufactured at Cidra the 17 drugs plaintiffs have identified as "At- Issue" in this matter. Am. Compl. ¶ 3." GSK SUMF ¶ 61.
- "On March 4, 2005, the FDA issued a press release titled "U.S. Marshals Seize Lots of GlaxoSmithKline's Paxil CR and Avandamet Tablets Because of Continuing Good Manufacturing Violations." *See* Cale Ex. 30 (Ex. 74). The release stated in part: 'In response to ongoing concerns about manufacturing quality, the Food and Drug Administration (FDA) and the Department of Justice today initiated seizures of Paxil CR and Avandamet tablets

[3] Plaintiffs aver that these statements by be admitted as judicial admissions, admissions of a party opponent, by means of judicial notice and/or on other grounds.

manufactured by GlaxoSmithKline, Inc. (GSK). Manufacturing practices for the two drugs…failed to meet the standards laid out by FDA that ensure product safety, strength, quality and purity.' " GSK SUMF ¶ 79.

- "On May 5, 2005, the FDA entered into a consent decree with GSK and SB Pharmco. Consent Decree of Condemnation and Permanent Injunction, *United States v. Undetermined Quantities of Articles of Drug*, No. 5:05-cv-141-FL(1) (E.D.N.C. May 5, 2005) (Ex. 78)." GSK SUMF ¶ 85.
- "As a result of the Consent Decree, GSK hired a third-party auditor, Quantic Regulatory Services ("QRS") to evaluate and inspect manufacturing operations at the plant. GSK-ECK-0010-018713 (Ex. 79)." GSK SUMF ¶ 87.
- "In 2004, Ms. Eckard filed a False Claims Act complaint against GSK related to the cGMP compliance issues she had identified for FDA. U*.S. ex rel. Cheryl Eckard v. GlaxoSmithKline, et al*., No. 04-10375 (D. Mass.). Following the DOJ and FDA investigation into the manufacturing operations at Cidra, GSK and SB Pharmco paid $600 million to resolve Ms. Eckard's False Claims Act suit. See Settlement Agreement, *U.S. ex rel. Cheryl Eckard v. GlaxoSmithKline, et al.*, No. 04-10375 (D. Mass. Oct. 21, 2010) (Ex. 85)." GSK SUMF ¶ 8.

Statements made by GSK's then CEO J.P. Garnier on behalf of GSK, including:

- "GSK said it will need to work through the GMP issues as quickly as possible in order to launch Avandaryl….[CEO J.P. Garnier said, 'The consent decree] is basically a 'get better' plan in terms of GMPs at Cidra. **We expect to be able to do that fairly rapidly**.'….The company believes it may be possible to ship a large portion of the seized product. '**Most of it is actually okay, even though it was seized**,' Garnier said….During the call, GSK was asked whether it was underestimating the impact of the consent decree in light of the effect that GMP problems have had on other large pharmaceutical companies…**GSK said the Cidra GMP violations are more contained** than those at Lilly's facilities….[Garnier said, '**They had a system problem. They had things…which were much wider and much deeper than what we have**.'… 'As you increase the complexity, GMP principles get more difficult. **It's just business as usual, just the plant was a bit overstressed**,' Garnier maintained. '**I wouldn't call it a sloppy operation.**'" GSK SUMF Ex. 119.

Statements made by GSK's corporate representative Kirk Brown on behalf of GSK, including:

[redacted]

[redacted]

[redacted]

[redacted]

Dated: November 1, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 1, 2019, I served the foregoing Plaintiffs' Pretrial Memorandum by ECF on the following counsel:

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